

DOCUMENT-IDENTIFIER: US 5368591 A
TITLE: Heated balloon catheters

ABPL:

Device and method for heating tissue, the device having a catheter shaft for insertion into a patient's body, a chamber formed by a collapsible balloon mounted on the catheter shaft and filled with an electrically conductive fluid, two or more electrical contacts enclosed within the chamber, a power supply for applying an electrical potential to the contacts, and a two or more conductors for connecting each of the contacts to the power supply. The fluid is heated on the basis of I.sup.2 R losses by a radio frequency electric current flowing between the electrodes, and the fluid in turn heats the surrounding tissue by heat transfer through the wall of the chamber. According to the method, the apparatus is inserted into the patient's body, the chamber is filled with an electrically conductive fluid, and an electrical potential is applied to the contacts. The apparatus functions as a temperature source. A thermister sensor in the balloon or in contact with tissue responds to the heating effect to control the application of the current. Advantageously, by periodic sensing of temperature, and application of controlled rf power, a preset constant temperature is maintained at the selected sensing point, either at the internal body site or the liquid within the balloon. In this way carefully controlled therapy can be conducted at constant temperature.

DEPR:

Referring to FIG. 5, another embodiment of the invention is shown in which temperature sensor 26 is placed in direct contact with tissue 44, outside of balloon catheter 34. Wires 60 and 62 connect temperature sensor 26 with

temperature control circuit 52, and wires 20 and 18 connect electrodes 22 and 24 respectively with RF power supply 50. Temperature control circuit 52 regulates RF power supply 50 in response to the input from temperature sensor 26.

DEPR:

Referring to FIG. 6, another embodiment of the invention is shown in which the temperature sensor consists of a pressure transducer 64 in conjunction with pressure sensing circuit 66 and pressure-to-temperature conversion circuit 68.

In this embodiment, the electrodes 22 and 24 are small enough that the electric current density in the immediate vicinity of the electrodes can induce localized boiling, which aids in the convection of heat from the electrodes to the surrounding tissue 44. The balloon material is heat-set at a temperature in excess of 100.degree. Celsius, so that the balloon material remains dimensionally stable when the fluid 36 within the balloon 8 boils at about 100.degree. Celsius. A flexible tube 70 provides a conduit for fluid into lumen 14 of catheter shaft 10. Inflator 72 is used to inject fluid into flexible tube 70 until a desired pressure is obtained, as indicated by pressure gauge 74. When RF power supply 50 is activated, the high electric field density in the immediate vicinity of each of the electrodes 22, 24 can induce localized boiling of fluid 36. As the fluid 36 heats up, the boiling increases in intensity. The boiling causes the pressure inside balloon 8 to increase. The increase in pressure is measured by pressure transducer 64, as an indirect indication of the amount of heating of the fluid 36, according to pressure/temperature relationships. Temperature control circuit 52 regulates RF power supply 50 in response to the input obtained from pressure-to-temperature conversion circuit 68. Temperature display circuit 76

displays the temperature obtained from pressure-to-temperature conversion circuit 68. Impedance stability sensor 78 detects the initiation of boiling by sensing the instability of catheter impedance due to the formation of vapor at the surfaces of electrodes 22 and 24.

DEPR:

Referring to FIG. 1, balloon catheter 34 may be used as a heat source during or after angioplasty to seal the splitting of the intimal layers of the wall of blood vessel 42 that occurs during angioplasty, and to mold the vessel wall. The blood vessel may be a coronary artery, or a peripheral artery such as an iliac, femoral, renal, carotid, or popliteal artery. The user first preselects the desired therapeutic temperature (temperature set voltage 92, FIG. 7), and sets the length of time for which balloon 8 is to be heated (time set switches 112, FIG. 6). A percutaneous insertion is made with a needle, and guide wire 46 is introduced into the blood vessel 42. Balloon catheter 34 follows the wire. If balloon 8 contains conductive radiopaque fluid, the location of balloon 8 can be monitored by means of fluoroscopy. Balloon 8 is inflated through lumen 14 with either saline, a conductive radiopaque fluid, or a mixture of saline and a radiopaque fluid, to a pressure of 4 to 17 atmospheres, in order to expand the wall of blood vessel 42. The balloon remains inflated for about 20 seconds or longer, depending on the particular blood vessel upon which the angioplasty is being performed. Either during or after the plastic deformation of the vessel wall, with balloon 8 inflated to at least a low level of pressure, the user depresses footswitch 122 (FIG. 7) to initiate the bi-polar heating between the electrodes 36. Heat is dissipated into the fluid according to the formula $P = I^2 R$ where P is the power that is dissipated into the fluid, I is the current that is passed through the

electrodes, and R
is the resistance of the fluid. The heat from the fluid is
conducted across
the balloon wall into the surrounding tissue 44. For angioplasty
procedures,
RF power supply 50 supplies a maximum current of 1/4 amp, and the
power
dissipated into fluid 36 is about 10 to 25 watts. The fluid will
heat to the
temperature set by the user, which may be in the range of
45.degree. Celsius
to 80.degree. Celsius. Heating will continue until the time set
by the user
has elapsed, or until the user deactivates footswitch 122.

DOCUMENT-IDENTIFIER: US 6283989 B1

TITLE: Method of treating a bronchial tube with a bronchial stenter having diametrically adjustable electrodes

DEPR:

FIGS. 1A and 1B show that electrodes 102 and 104 are connected via cables 122 and 142, respectively, to a radio frequency (RF) generator 130 with controls 138. Rod 110 is also connected to syringe 150 which is employed to inject a fluid from source 146 through valve 148 into the balloon.

DEPR:

The amount of inflation of the balloon is determined by the operating surgeon who monitors the balloon expansion by means of endoscopy or by other suitable imaging methods of the art. Generally, the heat required is induced in the tissue of the bronchial tube wall by the RF or microwave radiation emitting from the electrodes. The RF or microwave energy would be applied while observing for changes via simultaneous endoscopy, or other suitable imaging methods of the art.

DEPR:

Alternatively, heat treatment apparatuses employing a unipolar electrode can also be employed. For instance, in the case of the embodiment shown in FIGS. 1A and 1B, the heating device can have one or more inner electrodes 102 and/or 104 on the balloon surface and an outer or external electrode 188 that has a much larger surface area than that of the internal electrode(s) and that is placed on the outer surface of the patient's body. For example, the external electrode can be an external metal mesh or solid plate that is placed on the skin. Both the internal and external electrodes are connected to an RF generator which produces an electric field at a high frequency

within the balloon. Because the collective surface area of the internal electrode(s) is much smaller than that of the outer electrode, the density of the high frequency electric field is much higher around the internal electrode(s). The electric field reaches its highest density in the region near the internal electrode(s). The increased density of the field around the internal electrode(s) produces localized heating of the tissue.

DEPR:

As is apparent, the heat treatment device of the present invention can comprise more than one electrode that is positioned at or near the distal end of the elongated rod. For example, FIG. 7 depicts schematically the distal end 700 of a heat treatment device which comprises electrodes 701, 702, and 703. In this configuration if the device operates in the bipolar mode, two of the three electrodes (e.g., 701 and 702) are connected to one pole of the RF generator and the other electrode (702) is connected to the other pole. Heat will be generated in the tissue adjacent the region between electrodes 701 and 702 and the region between electrodes 702 and 703. These electrodes 701, 702, and 703 can be attached to the exterior surface of a balloon, alternatively they represent adjustable coils in embodiments that do not require a balloon.

DOCUMENT-IDENTIFIER: US 6251109 B1

TITLE: Process and device for the treatment of atrial arrhythmia

BSPR:

The present invention is an ablation catheter useful for ablation procedures

within a vessel of a human, or on the os of that vessel,

particularly a

pulmonary vein. A first and a second balloon are secured to the catheter, with

the second balloon secured to the catheter and located inside the first

balloon. The balloons, when inflated, seal the vessel and prevent

substantially the flow of blood through the vessel around these balloons. An

introduction system is also included as an element of the ablation catheter to

introduce a conductive media to the space within the first and second balloons

when inflated. The first balloon contains a plurality of balloon openings in

its outside surface through which the conductive media is

expelled to contact

the tissue of the vessel. An ablating system is also included as an element of

the ablation catheter, which system is secured to the catheter at a location

within the first, outer balloon, but outside of the second, inner balloon. The

ablating system includes one or more Rf energy ablation

electrodes, which may

be in the form of a coil electrode or a ring electrode. The

conductive media

conducts the ablating energy from the ablating system out through the balloon

openings in that first balloon to contact the tissue located in the vessel, or

on the Os of the vessel, adjacent to the balloon openings to form a

circumferential ablation lesion in the vessel or on the os of the vessel.

DEPR:

The ablating system, preferably a pair of Rf coil electrodes

(30), or ring

electrodes (130), which are secured to the outer surface (13) of

the catheter
(12) at a location within the outer balloon (20) and outside of
the inflated
inner balloon (22), then emit energy which is conducted by the
conductive media
through the balloon openings (28) in the surface (34) of the
outer balloon (20)
to the surface of the tissue in the pulmonary vein (14).
Sufficient energy is
emitted to create a circumferential lesion of sufficient width
and depth to
block completely the passage of the atrial premature contractions
through the
pulmonary vein (14). The temperature of the tissue of the
pulmonary vein (14)
may be monitored by temperature sensors, such as thermistors or
thermocouples
(not shown), located on the surface (13) of the catheter (12)
outside the
balloons (20, 22). In addition, sensing electrodes (not shown)
may be located
proximal from the balloons (20, 22) to sense electrical activity
through the
vessel after the ablation procedure has been completed to assure
complete
blockage of the pulmonary vein (14). The tissue to be ablated
may be at any
location within the pulmonary vein (14) or in the os of the
pulmonary vein
(14).

DOCUMENT-IDENTIFIER: US 6238392 B1

TITLE: Bipolar electrosurgical instrument including a plurality of balloon electrodes

BSPR:

In the above list of possible methods of heating tissue for treatment of Barrett's Esophagus, the application of RF energy has special interest, and in particular, the use of a RF balloon surgical instrument to deliver the energy to a body lumen or cavity. As described in U.S. Pat. No. 2,032,859 by F. C. Wappler, a RF balloon is especially effective for superficial desiccation or heating of tissue, such as the inner layer or lining of a lumen or cavity. The RF balloon described by F. C. Wappler was of monopolar design. Monopolar RF balloon devices use a first pole ground pad placed upon the exterior of the patient and a second (mono)pole balloon electrode placed within the patient and in contact with the diseased tissue. The second pole balloon electrode has an expandable made from a dielectric or non-conducting material, is filled with a conductive fluid, and has an electrode adjacent to the balloon and in contact with the conductive fluid. When applying RF energy to the human body with a bipolar electrosurgical device, it is important to establish firm contact with the tissue to reduce the possibility of burns. The balloon electrode, when inflated within a lumen or cavity within the body, expands outwards to adjust to the irregular contours of the lumen or cavity and firmly contacts the diseased tissue. The use of a non-conducting balloon as the tissue contact surface does not allow the direct coupling of RF energy to the tissue but rather forms a capacitive coupling with the tissue. The capacitive coupling of RF energy results in a gentle heating of the tissue in contact

with the balloon
electrode.

BSPR:

Whereas the Wappler bipolar RF balloon was indeed a breakthrough, the invention required the insertion of a limp or non-rigid balloon into a body lumen or cavity. Insertion of a non-rigid balloon into a muscular body cavity or lumen was difficult at best. Geddes et al. in U.S. Pat. No. 4,979,948 addressed this issue by describing a monopolar RF Balloon having a rigid elongated member extending longitudinally into the balloon. The elongated member is attached to the proximal base of the balloon and extends freely into the remainder of the balloon. This elongated member provides the necessary rigidity to support the un-inflated balloon during insertion into a body lumen or cavity. Additionally, the second pole electrode of this invention is placed around the elongated member extending within the balloon for contact with the electrolytic or conducting fluid used to expand the balloon.

BSPR:

What was needed was an RF balloon instrument that reduces the possibilities of uneven tissue heating or balloon burn through. U.S. Pat. No. 4,767,258 was issued to Kiyoshi Inokuchi et al. for a flexible monopolar balloon that attaches both proximally and distally to the distal end of a flexible shaft of the instrument. Whereas the Inokuchi et al. monopolar balloon utilized proximal and distal attachment of the balloon to the flexible shaft of the instrument, the monopolar design required the use of a second electrode that is placed on the outer circumference of the patient and the use of a constant flow of cooling fluid. An elongated resilient flexible electrode member (made from conductive material) that extends into an electrosurgical balloon is described in the F. C. Wappler U.S. Pat. No. 2,043,083.

BSPR:

All RF balloon inventions described above are monopolar and require the use of a return pole electrode or pad placed in contact with the exterior of the patient. U.S. Pat. No. 5,578,008 was issued to Shinji Hara for a bipolar balloon catheter wherein both the proximal and the distal end of the RF balloon is attached to the catheter (rigid support member) and has both (bipolar) electrodes located within the balloon. The bipolar RF balloon is fixed relative to both the catheter and reduces the possibilities of uneven heating described above. The bipolar electrode design heats the cooling liquid within the balloon and the heated liquid heats the tissue in contact with the balloon.

BSPR:

It would further be advantageous to provide the surgeon with a RF balloon electrosurgical instrument that can fit down the operating channel of an endoscope enabling the surgeon to visually place the balloon electrode at the surgical site. Shinji Hara in U.S. Pat. No. 5,578,008 and Jackson et al. in U.S. Pat. No. 4,676,258 describe the use of pulses or bursts to deliver energy from the electrosurgical generator to the balloon electrode. What is not disclosed in these inventions is the delivery of pulsed or burst RF electrical energy in a preset pattern to produce specific tissue effects.

DEPR:

The present invention is directed to an electrosurgical instrument for heating a lumen or a cavity within a patient. In particular, the present invention is directed to a bipolar electrosurgical instrument for the treatment of Barrett's Esophagus. A bipolar electrosurgical instrument according to one embodiment of the present invention uses a plurality of RF balloon electrodes to heat an inner lining or layer of the esophagus to destroy diseased

tissue, and to stimulate the regrowth of a new healthy inner lining. The embodiment illustrated is minimally invasive and requires the placement of the expandable RF balloon electrodes into contact with the inner lining of the esophagus for the application of RF electrical energy. One embodiment of a bipolar electrosurgical instrument 60 is shown in FIGS. 1-6 and FIGS. 9-11. Methods of using such a bipolar electrosurgical instrument according to the present invention are illustrated generally shown FIGS. 13-17

DEPR:

Flexible return sleeve 92 and flexible elongated tube 71 have hollow passageways for the passage of conductive fluid 74 to the balloon electrodes (FIGS. 5 and 17), and electrical wiring or conductors to conduct RF electrical energy to the balloon electrodes. The electrical wiring and hollow passageways from the elongated members are brought together at the return sleeve body 100. A balloon electrode fluid line 103 and a return balloon fluid line 102 are attached to the return sleeve body 100 for the passage of conductive fluid 74 to the balloon electrode 70a and to the return balloon electrode 90a, respectively, for the expansion of the balloon electrodes. The proximal ends of the balloon electrode fluid line 103 and the return balloon fluid line 102 are connected to a pressurized fluid source 51 for the expansion of the balloon electrodes. Bipolar electrosurgical instrument 60 has a connector cable 67 and an electrical connector 66 (FIG. 1) that are electrically connected to a RF generator 50 (FIG. 13). The RF (Radio Frequency) electrosurgical generator 50 provides RF energy to the electrosurgical instrument, preferably at a frequency between the range of 0.5 MHz to 20 MHz. The connector wire 67 is electrically connected to the balloon electrode 70a by a first pole wire 105 and to the

return balloon electrode 90a by first pole conductor 94.

DEPR:

The distal balloon electrode 70a and the flexible elongated tube 71 are shown in greater detail in FIGS. 4, 5, 6, and 9. Both the balloon electrode 70a and the flexible elongated tube 71 are filled with a conductive fluid 74 (FIG. 5) for the conduction of RF energy to tissue in contact with the balloon electrode 70a. To ensure contact between the balloon electrode 70a and the diseased inner lining of the esophagus, the balloon electrode 70a has an expandable sleeve 75 that is expanded by pressurizing the conductive fluid 74.

DEPR:

FIG. 5 shows a cross section view of the balloon electrode 70a and the elements within flexible elongated tube 71 and FIG. 6 shows an exploded view of these elements. A hollow spacer tube 78 is fixed (not shown) longitudinally within the flexible elongated tube 71. A first pole electrode 72 is fixedly attached about the spacer tube 78 and is located within and proximally recessed from both the distal end of the flexible elongated tube 71 and the expandable sleeve 75. The first pole electrode 72 is formed from wire braid and is electrically connected to the electrical connector 66 and the RF electrosurgical generator 50 (FIG. 13).

DEPR:

The elements of the expandable return balloon electrode 90a are shown in FIGS. 10, 11, and 17. The return balloon electrode 90a has an outer expandable return balloon sleeve 95 that forms a proximal and a distal hermetic seal with the flexible return sleeve 92, and a second pole electrode 91 within. It is important to note that the expandable return balloon sleeve 95 of the expandable return balloon electrode 90a has at least twice the surface area of

the expandable sleeve 75 of the balloon electrode 70a. Second pole electrode 91 is electrically isolated from contact with the patient 33 by the expandable return balloon sleeve 95 and the flexible return sleeve 92. The expandable return balloon sleeve 95 can be formed from the same materials as the expandable sleeve 75 described above and has a lower electrical permeativity than the flexible elongated tube 71 and the flexible return sleeve 92. A fluid passage 93 and a first pole conductor 94 run longitudinally within the flexible return sleeve 92 which is formed from a flexible engineering thermoplastic such as nylon, polyurethane, polyethylene, or the like (FIG. 17). The fluid passage 93 connects the return balloon electrode 90a with the return sleeve body 100 and the return balloon fluid line 102 for the passage of pressurized conductive fluid 74 to inflate the return balloon electrode 90a (dashed lines in FIG. 11). The first pole conductor 94 is electrically connected to the electrical connector 66 by the second pole electrode 91 and the connector cable 67 for the passage of RF energy. A distal sleeve 98 and a proximal sleeve 97 are used to attach and hermetically seal the expandable return balloon sleeve 95 to the flexible return sleeve 92. Like the balloon sleeve attachment methods described above, the expandable return balloon sleeve 95 is attached using heat shrinkable tubing (for the distal retaining sleeve 77 and the proximal retaining sleeve 76). Other hermetic attachment methods are available such as glue, heat staking, crimp fittings and the like.

DEPR:

FIG. 13 is a section view of the patient 33, showing the endoscope shaft 42 of the endoscope 40 insertion into the mouth 26 and esophagus of a patient 33.

The bipolar electrosurgical instrument 60 is attached to the endoscope and the balloon electrode 70a is extending distally from the operative

channel 43 (FIG.

2) of the endoscope 40. The expandable sleeve 75 of the balloon electrode 70a is expanded into contact with the inner lining 29 of the esophagus 25 by the connection of the balloon electrode fluid line 103 to the pressurizable fluid source 51. The endoscope shaft 42 is curved to place the un-expanded return balloon electrode 90a into contact with the inner lining 29 of the esophagus 25 to provide the return path for the electrical energy. The return balloon electrode 90a is larger in diameter than the balloon electrode 70a and need not be expanded if enough surface area of the expandable return balloon sleeve 95 is in contact with tissue. The electrical connector 66 of the bipolar electrosurgical instrument 60 is connected to the RF electrosurgical generator 50.

DEPR:

FIG. 14 shows the placement of the balloon electrode 70a at the site of the columnar epithelium 30 prior to the application of RF energy to the diseased area of the inner lining 29. The balloon electrode 70a is visible in a viewing angle 46 of the viewing optics 44 and the surgeon has visually maneuvered the balloon electrode 70a into contact with the columnar epithelium 30. Ideally, this maneuvering is done prior to the expansion of the expandable sleeve 75. The expandable sleeve 75 is shown expanded to contact the diseased columnar epithelium 30.

DEPR:

FIGS. 15 and 16 shows the placement of the return balloon electrode 90a of the bipolar electrosurgical instrument 60 just prior to the application of RF energy. Both the balloon electrode 70a and the return balloon electrode 90a are expanded and in contact with tissue. In FIG. 16, the balloon electrode 70a is contacting the columnar epithelium 30 found on the inner

lining of the esophagus 25 and the return balloon electrode 90a is moving from the initial position shown in FIG. 15 to the final position shown in FIG. 16.

This movement spaces the return balloon electrode 90a the previously described distance "L" from the balloon electrode 70a and the effects of this action will now be described.

DEPR:

FIG. 20 is a cross sectional view along the longitudinal axis of an alternate embodiment of a bipolar dual balloon end effector 120. Instead of a single balloon electrode 70a at the distal end of the flexible elongated tube 71, the dual balloon end effector 120 of the alternate embodiment has a pair of expandable electrodes side by side in a longitudinal orientation.

FIG. 20 is a cross sectional view taken perpendicular to the longitudinal axis of the dual balloon end effector 120 and shows a cross section of a first pole balloon electrode 125 on the left and a cross section of a second pole balloon electrode 130 on the right. First pole balloon electrode 125 and second pole balloon electrode 130 are separated by an isolator wall 121 to prevent contact between the balloon electrodes and are backed by a proximal end plate 122.

Each balloon electrode 125, 130 is identical to and a mirror image of the other. The first pole balloon electrode 125 has a first pole balloon sleeve 126 that is expandable by the addition of conductive fluid 74 from the pressurizable fluid source 51. The conductive fluid 74 is conducted into the first pole balloon sleeve 126 by a first pole fluid passage 127 that extends through the flexible elongated tube 71 that is connected to the pressurizable fluid source 51. A first dual electrode 128 is recessed into the proximal end plate 122 for the delivery of electrical energy to the first pole balloon

electrode. Like the mirror image first pole electrode 125 described above, the second pole electrode 130 has a second pole balloon sleeve 131, a second pole fluid passage 132, and a second dual electrode 133. The application of RF energy to bipolar dual balloon end effector 120 heats the adjacent tissue by capacitive coupling much in the manner described above. Heating effects from this design are more pronounced along a horizontal plane that runs through the first dual electrode 128 and second pole balloon fluid passage 132. Less heating is found along a vertical plane established by the isolator wall 121. This type of end effector provides the surgeon with localized and opposite lobes of heating which can leave healthy tissue between the lobes unscathed.

DEPR:

FIG. 25 shows yet another alternative embodiment of an alternate bipolar electro-surgical instrument 140 wherein the alternate embodiment has a multiplicity of expandable electrodes spaced longitudinally along the longitudinal axis of the alternate bipolar electro-surgical instrument 140. In FIG. 21, three balloon electrodes are shown, distal balloon electrode 70a, return balloon electrode 90a, and an alternate balloon electrode 141 located proximally from return balloon electrode 90a. A switching network 142 is provided to switch the application of bipolar RF energy from the distal balloon electrode 70a and the return balloon electrode 90a to the alternate balloon electrode 141 and the return balloon electrode 90a. This switching effectively enables the surgeon to move the application of RF energy from the distal most balloon electrode 70a to the proximal most alternate balloon electrode 141 without moving the bipolar electro-surgical instrument 120. It is important to note that the central return balloon electrode 90a is at least twice the size

of the proximal alternate balloon electrode 141 and the distal balloon electrode 70a. Also of note is the distance "L" between the pair of selected balloon electrodes is at least twice the longitudinal length of the return balloon electrode 90a or alternate balloon electrode 141. This ensures that the smaller of the two balloon electrodes selected has the highest current density surrounding it to confine tissue-heating effects to tissue directly adjacent to the smaller balloon electrode.

DEPR:

In yet another embodiment of the invention and as shown in FIGS. 22-24 the output of the RF electrosurgical generator 50 to the bipolar balloon electrodes is altered from a continuous sinusoidal output 150 (FIG. 22) to a pulsed "burst" mode 155 (FIG. 24). The output of a RF generator 51 in cautery mode is a continuous sinusoidal output 150 of a frequency dependent on the generator and at a typical current of 0.75 to 1 amps (FIG. 23). In "burst" mode 155, the sinusoidal output 150 of the generator is retained but the application of the waveform to tissue is broken up into discrete "bursts" or pulses of energy separated by periods of no energy application. The bursts of energy 156 are applied for approximately 2-100 milliseconds, and most preferably around 10 milliseconds. The bursts of energy 156 are applied at a rate of 2 to 500 Hz and most preferably between 50-100 Hz. The current 151 applied during the pulse is increased to between 1.5 to 5 amps and most preferably at 2 amps. Providing bursts of increased current 151 results in the average power being kept between 2-100 watts and most preferably below 20 watts. By providing short bursts of energy 156 of higher current 151, the net energy applied to the tissue is less or equal to the energy applied by the steady sinusoidal output 150 of an unmodified RF generator.

DEPR:

Testing has shown that the application of pulsed RF energy in the manner described above results in decreased internal heating of the conductive fluid within the balloon electrode, and limits the depth of penetration of the RF energy into the wall of the lumen. Additionally, tissue effects produced by the bursts of energy 156 are visually different from tissue treated with a continuous output sinusoidal waveform 150, and have more of a "sunburned tissue" effect than the more typical "cooked tissue" effect produced by the application of continuous sinusoidal RF energy.